43 ~~41~~. (new) A pharmaceutical composition according to claim ~~30~~ 32 in which the composition is a lotion.

44 ~~42~~. (new) A pharmaceutical composition according to claim ~~30~~ 32 in which the composition is a gel.

45 ~~43~~. (new) A pharmaceutical composition according to claim ~~30~~ 32 in which the composition is a cream.

46 ~~44~~. (new) A pharmaceutical composition according to claim ~~31~~ 33 in which the composition is a lotion.

47 ~~45~~. (new) A pharmaceutical composition according to claim ~~31~~ 33 in which the composition is a gel.

48 ~~46~~. (new) A pharmaceutical composition according to claim ~~31~~ 33 in which the composition is a cream. --

REMARKS

Applicants respectfully request reconsideration of the application in view of the foregoing amendments and following remarks.

Claims 19-26 were pending in the instant application when it went up on appeal and all stood finally rejected. The Appeal Board vacated the Examiner's rejection of claims 19-26 and entered new grounds of rejection as to claims 19-26.

Applicants have hereby canceled claims 19-26 without prejudice and have replaced them with new claims 27-46. Support for the new claims can be found in the specification as follows:

Claim	Support
27	Claims 19 and 23
28	Claim 19; page 14, lines 8-14; and page 16, last paragraph, i.e. lines 15-19
29	Claim 19; page 14, lines 15-21; and page 16, last paragraph, i.e. lines 15-19
30	Claim 19; page 15, lines 1-7; and page 16, last paragraph, i.e. lines 15-19
31	Claim 19; page 15, lines 8-14; and page 16, last paragraph, i.e. lines 15-19

In addition to the above, support for claims 32 – 46 can be found, e.g., in original claims 24 – 26.

Applicants submit no new matter has been added by the present amendment.

The rejection of claims 19-26 under 35 USC 103(a) as being unpatentable over (1) European Patent Application, EPA 0 184 162 (hereinafter "EPA"), (2) Johnson, US Patent No. 4,411,893 and (3) Showalter, US Patent No. 4,556,654 is respectfully traversed.

The presently claimed invention is directed to pharmaceutical compositions for **topical** administration in the form of a lotion, gel, or cream comprising 1% to 3% of a compound as described in claims 27 – 31 and a carrier for a lotion, gel or cream, said carrier being a carrier for topical administration. The compositions are useful in **topically** treating inflammatory or hyperproliferative **skin** diseases or **cutaneous** manifestations of immunologically-mediated illnesses, such as psoriasis, atopical dermatitis, contact dermatitis and further eczematous dermatitises, seborrhoeic dermatitis, Lichen planus, Pemphigus, bullous Pemphigoid, Epidermolysis bullosa, urticaria, angioedemas, basculitides, erythemas, cutaneous eosinophilias, Lupus erythematosus or Alopecia areata.

It is the Board's position that the instant compounds fall within the scope of those disclosed in EPA, EPA suggests their use as antimicrobial agents to be applied with a carrier "externally", "externally" means "topically" and then cites Johnson and Showalter as evidence that "The prior art is well aware of how antimicrobial agents are applied topically using lotions, gels and creams." Applicants don't dispute the compounds of claims 27-31 fall generically within the scope of EPA. Applicants agree EPA suggests the use of the compounds as antimicrobials and that it contemplates "external" administration. However, applicants disagree with the board that "externally" as used in EPA means "topically". To the contrary, applicants submit "external" administration as contemplated by EPA does not contemplate topical administration.

While EPA teaches its compounds have antimicrobial activity, it is submitted the antimicrobial activity is that which is treated systemically as evidenced by the antimicrobial test 2 set out on pages 70-71. The fungi used in test 2 were Aspergillus Fumigatus and Fusarium Oxysporum, organisms which are treated systemically. There is nothing in EPA to teach or suggest the compounds would have topical efficacy as antimicrobial agents. In fact, all the conditions disclosed by EPA require systemic treatment. This is not surprising since, as discussed on pages 2 and 3 of the instant specification, the topical efficacy of the claimed compounds is totally

unexpected in light of the results found with the known cyclic immunosuppressant, cyclosporin. There is nothing in EPA which would suggest that, unlike cyclosporin, the claimed compounds would exhibit surprising topical activity; and there is certainly nothing which could possibly motivate one skilled in the art to investigate the topical treatment of the conditions disclosed EPA, all of which require systemic treatment. From the teachings of the EPA reference, one skilled in the art would recognize that the external administration contemplated by EPA clearly involves those modes of external administration, such as nasal, buccal, rectal, etc. routes, which could produce a systemic effect, not topical administration which has a local effect.

The Board states that "Applicants have apparently overlooked the fact that EPA teaches that its compounds have antimicrobial activity and the prior art has long applied antimicrobial compounds to skin... in the form of lotions, gels and creams". As set forth above, Applicants don't dispute that antimicrobial compounds have been applied to the skin in the past however what applicants do dispute is that EPA teaches its compounds as antimicrobials to be applied topically to the skin. It is submitted antimicrobials can be applied systemically as well as topically. As set forth above, the fungi tested by EPA are those which are known to be treated systemically. The currently contemplated topical administration is for a non-systemic beneficial effect at the site of administration.

In view of the foregoing, applicants submit that EPA does not disclose a single utility for the claimed compounds which can be beneficially treated locally and the cyclosporin art teaches that such compounds are not effective when administered in conventional topical forms. It is clear that Applicants pharmaceutical compositions could only be arrived at by disregarding the substance of EPA's teachings and the prior art as a whole. There is no way that one skilled in the art guided by EPA's disclosure and examples would be led to applicants' topical pharmaceutical compositions without direction from the instant application.

It is submitted Johnson and Showalter fail to make up for the deficiencies of EPA.

Accordingly, it is believed claims 27-46 are patentable over EPA alone or in combination with Johnson and/or Showalter.

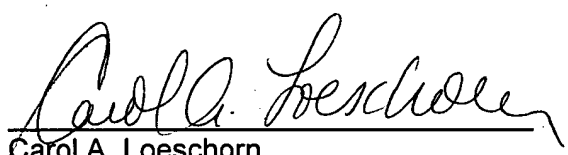
The rejection of "Claims 19-22 and 24-26... under 25 USC 112, first paragraph, because the specification does not contain an enabling description commensurate in scope with the breadth of the rejected claims" is believed to have been overcome by the amendments to the claims.

Applicants have limited the claims to the five compounds, i.e. compounds A – E set forth on pages 14 and 15 of the specification. The topical efficacy of these compounds is shown in the models set forth on pages 4 – 12 of the specification. Applicants submit the instant claims, being limited to compounds A – E, fully meet the enablement requirements of 35 USC 112, first paragraph.

In view of the foregoing, applicants submit claims 27 – 46 are in condition for allowance. An early notice to that effect is earnestly solicited.

Authorization is hereby given to charge the fee of $168.00 pursuant to 37 CFR 1.16(b) for the two independent claims in excess of three now present in the application, to Deposit Account No. 19-0134 in the name of Novartis Corporation. An additional copy of this page is being submitted herewith for the purpose of charging such fee. It is believed no additional fees are necessitated by the instant amendment. However, in the event of any additional fees, please charge such fees to Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,



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